

# **EXHIBIT B**

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

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<b>IN RE ETHICON, INC., PELVIC REPAIR</b>	:	<b>CIVIL ACTION NO. 2:12-md-02327</b>
<b>SYSTEM PRODUCTS LIABILITY</b>	:	
<b>LITIGATION</b>	:	<b>MDL No. 2327</b>
-----	:	
	:	Judge Joseph R. Goodwin

This Document Applies To All Actions

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**PLAINTIFFS' FIRST REQUEST FOR  
PRODUCTION OF DOCUMENTS TO DEFENDANTS**

Pursuant to Fed. R. Civ. P. 34, Plaintiffs in the above-referenced cases Request Defendants Johnson & Johnson, Ethicon, Inc., Ethicon SARL, Ethicon SAS, Ethicon LLC, Johnson and Johnson Medical LTD, Johnson and Johnson Medical GMBH (collectively, "Ethicon" and/or "Defendants"), produce and permit the Plaintiffs' Steering Committee ("PSC") to inspect and copy the documents listed below.

**DEFINITIONS**

1. "DOCUMENTS" and "DOCUMENTATION" as used in this Request is coextensive with the meaning of the terms "DOCUMENTS" and "tangible things" in Fed. R. Civ. P. 34, and shall have the broadest possible meaning and interpretation ascribed to the terms

“DOCUMENTS” and “tangible things” under Fed. R. Civ. P. 34, and the applicable Local Rules. Consistent with the above definition, the term DOCUMENT shall include, without limitation, any database, written, printed, typed, photostatic, photographed, recorded, computer-generated, computer-stored, or otherwise maintained or reproduced communication or representation, any data compilation in any form, whether comprised of letters, words, numbers, pictures, sounds, bytes, e-mails, electronic signals or impulses, electronic data, active files, deleted files, file fragments, or any combination thereof including, without limitation, all memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, projections, estimates, working papers, accounts, analytical records, reports and/or summaries of investigations, opinions or reports of consultants, opinions or reports of experts, opinions or reports of accountants, other reports, trade letters, press releases, comparisons, books, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, forecasts, drawings, diagrams, instructions, minutes of meetings, correspondence and communications (as defined below) of any type (including but not limited to video files, audio files, inter- and intra-office communications), questionnaires, surveys, charts, graphs, photographs, phonographs, films, tapes, discs, data cells, drums, printouts, all other compiled data which can be obtained (translated, if necessary, through intermediary or other devices into usable forms), DOCUMENTS maintained on, stored in or generated on any electronic transfer or storage system, any preliminary versions, drafts or revisions of any of the foregoing, and other writings or DOCUMENTS of whatever description or kind, whether produced or authorized by or on behalf of YOU or anyone else, and shall include all non-identical copies and drafts of any of the foregoing now in the possession, custody or control of YOU, or the former or present

directors, officers, counsel, agents, employees, partners, consultants, principals, and/or persons acting on YOUR behalf.

2. “Communication” and/or “correspondence” shall mean and refer to any oral, written, spoken or electronic transmission of information, including but not limited to, meetings, discussions, conversations, telephone calls, memoranda, letters, emails, text messages, postings, instructions, conferences, or seminars or any other exchange of information between yourselves or between you and any other person or entity.

3. “Computer” means all devices utilizing microchips to facilitate processing, analysis, or storage of data, including microcomputers (also known as personal computers), laptop computers, portable computers, notebook computers, palmtop computers (also known as personal digital assistants or PDA’s), minicomputers and mainframe computers. “Computer system,” when used in reference to any computer, includes the following information: (a) the computer type, brand, and model, and (b) the brand and version of all software, including the operating system, private- and custom-developed applications, commercial applications, and/or shareware.

4. “Electronic data” or “data” means the original (native electronic format), and any non-identical copies (whether non-identical because of notes made on copies or attached comments, annotations, marks, transmission notations, or highlighting of any kind) of writings of every kind and description whether inscribed by mechanical, facsimile, electronic, magnetic, digital, or other means. Electronic data includes, by way of example only, computer programs (whether private, commercial, or works-in-progress), programming notes or instructions, activity listings of electronic mail receipts and/or transmittals, output resulting from the use of any software program, including word processing documents, spreadsheets, database files, charts,

graphs and outlines, electronic mail, operating systems, source code of all types, peripheral drivers, PIF files, batch files, ASCII files, and any and all miscellaneous files and/or file fragments, regardless of the media on which they reside and regardless of whether said electronic data consists of an active file, deleted file or file fragment. Electronic data includes any and all items stored on computer memories, hard disks, floppy disks, CD-ROMs, removable media such as zip drives, usb drives, storage cartridges, Bernoulli Boxes and their equivalent, magnetic tapes of all types, microfiche, punched cards, punched tape, computer chips, including, but not limited to EPROM, PROM, RAM and ROM, on or in any other vehicle for digital data storage and/or transmittal. The term electronic data also includes the file, folder tabs and/or containers and labels appended to, or associated with, any physical storage device associated with each original and/or copy.

5. “Electronic media” means any magnetic or other storage media device used to record electronic data. Electronic media devices may include computer memories, hard disks, floppy disks, CDROM, removable media such as Bernoulli Boxes and their equivalent, magnetic tapes of all types, microfiche, punched cards, punched tape, computer chips, including, but not limited to EPROM, PROM, RAM and ROM, or on or in any other vehicle for digital data storage and/or transmittal.

6. “Identify” or “identity” with respect to persons, means to give, to the extent known, the person’s full name, present or last known address, and when referring to a natural person, additionally, the present or last known place of employment.

7. “Native Electronic Format” shall mean and refer the state of an electronic file as it presently exists on any and all computers, electronic media devices, networks or any other locations where data may be stored (including back-up servers, deleted folders, hidden folders,

etc.), with all of the file's original metadata intact, meaning that the metadata fields have not been altered, deleted, updated or modified in any way.

8. "Network" means any hardware and/or software combination that connects two or more computers together and which allows the computers to share and/or transfer data between them. For the purposes of this definition, the connection between or among the computers need not be either physical or direct, *i.e.*, wireless networks, and sharing and/or transferring data via indirect routes utilizing modems and phone company facilities. In addition, there need not be a central file or data server nor a central network operating system in place, *i.e.*, peer-to-peer networks and networks utilizing a mainframe host to facilitate data transfer.

9. "Person" means natural person, as well as corporate and/or governmental entity.

10. "Possession, custody or control" shall mean and refer to any documents in your possession, custody or control. A document is deemed to be in your "possession, custody or control" if it is in your physical custody, or if it is in the physical custody of another person or entity and you: (a) own such document in whole or in part; (b) have a right by contract, statute or otherwise to use, inspect, examine or copy such document on any terms; (c) have an understanding, express or implied, that you may use, inspect, examine or copy such document on any terms; or (d) have, as a practical matter, been able to use, inspect, examine or copy such document when you have sought to do so. Such documents shall include, without limitation, documents that are in the custody of your attorney(s), employees, staff, representatives and agents.

11. The term "Pelvic Mesh," or "Pelvic Mesh Products" shall include any product advertised, analyzed, assembled, designed, developed, distributed, engineered, inspected, labeled, manufactured, marketed, packed, produced, promoted, processed, researched, sold

and/or tested by Johnson & Johnson Inc., its predecessors in interest, subsidiaries, agents, representatives, servants and/or employees under the trade names Prolene mesh, Prolene Soft (PS), Prolift, Prolift +M, Prosima, TVT, TVT-Obturator, TVT-Secur, TVT-Exact, TVT-Abbrevio, TVT-Catheter Guide, TVT-Introducer, Gynecare TVT Family of Products, Gynecare TVT Retropubic System Tension-Free Support for Incontinence, Gynecare Family of Products for Pelvic Floor Repair, in the United States, or any other trade name outside the United States. This shall also include any “kits” which contain any of these products, any components of these kits such as cannulas and trocars as well as any predecessor or successor products which are designed intended to be surgically used in pelvic floor repair or to treat urinary incontinence developed, in development, or marketed by Defendants.

12. “Hernia Mesh Products” is used to refer to any mesh product intended for use in hernia repair, developed, in development, or sold by Defendants.

13. “Complication” refers to any injury or disorder occurring in a patient caused by or potentially caused by Pelvic Mesh including, but not limited to: bleeding or clotting disorders, bowel obstruction, bowel perforation, chronic pain, cystocele, death, discomfort, dyspareunia, fistulas, impaired sexual relations, infection, incontinence, inflammation, mesh erosion, mesh exposure, mesh extrusion, pain, pelvic organ prolapse, pelvic tumors or fibroids, peritonitis/sepsis, ureteral obstruction, ureter obstruction, ureteral obstruction, urethral obstruction, urinary retention, vaginal or bladder infections, wound healing problems, and any other disease or disorder of the bowel, bladder, gut, intestines, uterus, or vagina.

14. “Other Pelvic Mesh Products” shall mean any products designed for and intended for use in the pelvic floor for the treatment of Stress Urinary Incontinence (SUI) or Pelvic Organ Prolapse (POP).

15. “Label” or “Labeling” refers to any draft or approved Product Insert, Patient Brochure, Instructions for Use (IFU), Final Printed Labeling, or any other documentation included in the prescription medication dispensed to patients, provided to surgeons, hospitals, or other physicians.

16. “Marketing” refers to any piece of material or collection of materials used to promote the use, sale, distribution, implantation or awareness of Pelvic Mesh Products includes, but is not limited to, public relations activities, press releases, talking points, junkets, physician training seminar materials, public statements, standby statements, posters, printed advertisements, video web postings, video advertisements, audio advertisements, internet advertisements and web postings, social media and twitter postings, news releases, promotional literature, public affairs material, product descriptions, product literature, books, medical journal articles, slim jims, notepads, calendars, office supplies, and all other such promotional materials.

17. “Study” or “Studies” refers to an examination, collection, compilation or analysis of data, including but not limited to product or event registries, controlled clinical trials, double-blind randomized trials, single-blind randomized trials, non-blinded trials, nonrandomized trials, experiments, meta-analyses, observational studies, prospective cohort studies, retrospective cohort studies, time series studies, case-controlled studies, ecological studies, cross-sectional studies, superiority trials, non-inferiority trials, equivalence trials, crossover studies, pharmacological studies, and any other type of epidemiological analysis. This includes studies conducted in animals, humans, chemicals, health databases, or any other data source.

A request for information concerning a Study that has been completed should be construed as including the following documents: the protocol for the conduct of the test/study, and amendment(s) to the protocol, documents or databases containing the original raw study



data, documents containing the written study report and all attachments thereto, any summary, abstract, analysis, compilation, including evaluation or interpretation of the study and all investigators or entities, facilities, firms, universities and/or laboratories involved in the testing.

18. “Test” or “Testing” refers to a procedure intended to establish the quality, performance, or reliability of a Pelvic Mesh Product, or one of its components, or a process concerning a Pelvic Mesh Product. “Testing” includes but not limited to product strength testing, toxicity testing, space of mesh openings (poreacity) testing, pigment testing, sterility testing, machine tolerance testing, engineering studies, machine testing, product absorption testing, durability testing, inertness testing, laser-cutting and machine-cut testing, and residual particle testing.

A request for information concerning a Test that has been completed should be construed as including the following documents: the protocol for the conduct of the test, and amendment(s) to the protocol, documents or databases containing the original raw test data, documents containing the written test report and all attachments thereto, any summary, abstract, analysis, compilation, including evaluation or interpretation of the test and all persons or entities, facilities, firms, universities and/or laboratories involved in the testing.

19. “Correspondence” shall mean any document or electronic message carried by the United States Postal Service, any private courier or courier service, telefax or telegraph, voice message, e-mail, internet posting, intranet posting, or tweet transferred or transmitted in any manner whatsoever.

20. “Relating to,” “relate to,” “referring to,” “refer to,” “reflecting,” “reflect,” “concerning,” or “concern” shall mean evidencing, regarding, concerning, discussing,

embodying, describing, summarizing, containing, constituting, showing, mentioning, reflecting, pertaining to, dealing with, relating to, referring to in any way or manner, or in any way logically or factually, connecting with the matter described in that paragraph of these demands, including DOCUMENTS attached to or used in the preparation of or concerning the preparation of the DOCUMENTS.

21. “Or” and “and” will be used interchangeably.

22. Unless otherwise indicated, the “relevant period” for the information sought is January 1992 to the present.

23. “YOU,” “YOUR,” “Ethicon” or “Defendants” refer to all domestic and foreign Defendants (both collectively and individually) as well as all of their partners, directors, officers, employees, servants, agents, attorneys, joint venturers, third-party contractors or other representatives, including all corporations and entities affiliated with Defendants. The terms “YOU” or “YOUR” shall also include all predecessor business entities, as well as any predecessor’s partners, directors, officers, employees, servants, agents, attorneys, joint venturers, third-party contractors or other representatives. The terms “YOU” or “YOUR” shall also include all foreign subsidiaries or foreign parent companies, as well as any foreign subsidiaries’ or parent companies’ partners, directors, officers, employees, servants, agents, attorneys, joint ventures or other representatives.

### **INSTRUCTIONS**

1. In responding to this Request, YOU are required to produce all DOCUMENTS known or reasonably available to YOU, regardless of whether such DOCUMENTS are in YOUR possession, custody, or control or in the possession, custody, or control of YOUR agents,

consignees, representatives or investigators, including YOUR attorneys or their agents, employees, representatives, or investigators.

2. If any of the DOCUMENTS or information Requested cannot be produced in full, YOU are required to specify, to the extent possible, the reasons for YOUR inability to produce the remainder, and the approximate date when YOU expect to produce such DOCUMENTS, if at all.

3. If any Request is deemed to call for the production of privileged or otherwise protected information or materials, YOU must provide the following information in a written response, designating and identifying those DOCUMENTS or information withheld from production on grounds of privilege:

- (a) The reason for withholding the DOCUMENT or information;
- (b) A statement of the legal basis for the claim of privilege, work product or other ground for non-disclosure;
- (c) A brief description of the DOCUMENT, including:
  - i. The date of the DOCUMENT;
  - ii. The number of pages, attachments, and appendices;
  - iii. The name(s) of its author(s) or preparer(s) and identification by employment and title of each such person;
  - iv. The name of each person who was sent, shown, or copied on the DOCUMENT, or has had access to or custody of the DOCUMENT, together with an identification of each such person;
  - v. The present custodian; and
  - vi. The subject matter of the DOCUMENT, and in the case of any DOCUMENT relating or referring to a meeting or conversation, identification of such meeting or conversation, in sufficient detail to enable the Court to determine the propriety of any claim of privilege.

4. Failure to properly identify any withheld DOCUMENTS may result in the waiver of any right to assert a privilege later.

5. This Notice and Request impose a continuing obligation upon YOU. If after producing DOCUMENTS or information responsive to this Demand additional information or

DOCUMENTS become available to YOU, YOU are required to produce such additional DOCUMENTS or information.

6. With respect to each DOCUMENT Requested that has been lost, destroyed, or otherwise disposed of since its preparation or receipt, YOU shall provide the following information separately as to each such DOCUMENT:

- (a) A general description of the subject matter, author, recipient(s), date;
- (b) The identity of each person who has received a copy or had an opportunity to receive a copy thereof;
- (c) The last custodian of the DOCUMENT or copies thereof; and
- (d) The full particulars or circumstances whereby the DOCUMENT was disposed of, destroyed, or otherwise lost.

7. All DOCUMENTS produced in response to these Requests shall be either:

- (a) Organized and labeled to correspond with the number of the specific Request to which the DOCUMENTS are responsive, or
- (b) Produced in the order and in the manner that they are kept in the usual course of business.

8. All DOCUMENTS Requested shall include all DOCUMENTS and information that relate in whole or in part to the relevant time period, or to events or circumstances during such relevant time period, even though dated, prepared or generated or received prior to relevant time period.

9. All DOCUMENTS that exist in electronic form are to be produced in electronic form and in their native electronic format, not in an electronic form that is merely a picture of a DOCUMENT such as a TIFF file, a TIF file, or a PDF file, with the Bates number applied in a manner that does not alter the DOCUMENT's metadata or its optical character recognition ("OCR") in any way.

10. Plaintiffs recognize that Ethicon is preparing to produce to the PSC several million pages presumptively in response to documents Requests served in the *In re Pelvic*

*Mesh/Gynecare* litigation, Case No. 291, coordinated before Judge Higbee in the Superior Court of New Jersey Law Division, Atlantic County. To the extent Defendants intend to re-produce the New Jersey production to the PSC, Defendants shall provide the Bates ranges of those documents responsive to each request therein, and a statement indicating whether or not a responsive production is complete for each request. Plaintiffs will not consider any prior production of DOCUMENTS responsive to these Requests unless the DOCUMENTS previously produced, where applicable, are produced in the format called for by these Requests.

### **DOCUMENTS TO BE PRODUCED**

#### **Corporate Organization and Policies and Litigation-Related Documents**

1. Corporate organization charts that identify each Defendants' corporate organizational structure during the relevant time period, including, but not limited to, charts that set forth the organization of the various departments, divisions and subdivisions, and the heads and/or employees of each such department, division or subdivision, and the relationship and/or overlap, if any, among and between defendants.
2. Documents sufficient to identify the role of each defendant with regard to Pelvic Mesh Products or Hernia Mesh Products (e.g., manufacturer, designer, distributor, marketer, etc.).
3. Any agreements among and between Defendants or any other person or entity relating to the development manufacturing, marketing and/or sale of Pelvic Mesh Products.
4. All Documents relating to all executive or board of director meetings, including copies of any reports, analyses, or presentations presented at such meetings, pertaining to the safety, complications, adverse events, efficacy, design, regulation, marketing, and sale of Pelvic Mesh Products.

5. All DOCUMENTS that reflect the policies and procedures that Defendants has had and/or has in place for the storage, deletion, and back-up of DOCUMENTS and emails generated by Defendants' employees and agents.

6. All logs, ledgers, and other such indices that reflect the identity and location of DOCUMENTS regarding PELVIC MESH PRODUCTS.

7. All DOCUMENTS concerning the steps taken by YOU to preserve all DOCUMENTS concerning, regarding, or pertaining to PELVIC MESH PRODUCTS.

8. All insurance policies, excess coverage policies, or any other type of insurance coverage, that YOU believe may potentially cover claims related to PELVIC MESH PRODUCTS.

9. Any deposition or other testimony provided by Defendants' employees or corporate representatives in connection with the *In re Pelvic Mesh/Gynecare* litigation, Case No. 291, coordinated before Judge Higbee in the Superior Court of New Jersey Law Division, Atlantic County, and/or any other court or administrative proceeding involving PELVIC MESH PRODUCTS.

10. All discovery responses provided by Defendants in connection with the *In re Pelvic Mesh/Gynecare* litigation, Case No. 291, coordinated before Judge Higbee in the Superior Court of New Jersey Law Division, Atlantic County, and/or any other court or administrative proceeding involving PELVIC MESH PRODUCTS.

11. Documents sufficient to identify all databases containing information responsive to these requests or otherwise relating to Pelvic Mesh Products or Hernia Mesh Products.

12. All DOCUMENTS concerning any inquiries or investigations by governmental or regulatory organizations within the United States (either state or federal) related to PELVIC MESH PRODUCTS, including documents submitted to or received from such organizations.

13. Any documents produced by YOU in any patent litigation relating to Pelvic Mesh Products.

14. Any documents produced by YOU in any personal injury litigation related to PELVIC MESH PRODUCTS.

**Documents Relating to Regulation of Pelvic Mesh Products**

15. All submissions, applications, correspondence, analyses, reports, memorandum, notes, telephonic and/or in-person meeting minutes to any United States government agency, including but not limited to the Food and Drug Administration, relating to any Pelvic Mesh Product or Hernia Mesh Products.

16. All submissions, applications, correspondence, analyses, reports, memorandum, notes, telephonic and/or in-person meeting minutes to any foreign government agency, including but not limited to the European Agency for the Evaluation of Medicinal Products (EMA), European Union (EU)-Therapeutic Goods Administration (TGA), Federal Institute for Drugs and Medical Devices (BfArM), Agence de Medicament, and the Medicines and Medical Devices Safety Authority, relating to the safety and/or efficacy of any Pelvic Mesh Products or Hernia Mesh Products.

17. Documents sufficient to identify all countries in which YOUR Pelvic Mesh Products or Hernia Mesh Products have been approved for sale and the date on which each was approved and/or cleared for use in the human body.

18. All DOCUMENTS relating to any Postmarket Surveillance Studies recommended or required by the FDA or any foreign regulatory body for YOUR Pelvic Mesh Products.

19. All DOCUMENTS relating to any Form FDA 483 Letters and/or FDA Warning Letters for YOUR Pelvic Mesh Products.

20. All DOCUMENTS relating to YOUR decision to cease commercialization or withdraw from market any YOUR Pelvic Mesh Products.

21. All DOCUMENTS concerning any governmental agency in any country worldwide that declined to approve an application to market PELVIC MESH PRODUCTS or for any indication, including, but not limited to, communications between the sponsor of PELVIC MESH PRODUCTS and the agency, and any English translations that exist if the DOCUMENTS are written in any language other than English.

22. All DOCUMENTS that concern, or involve discussion about, the potential or actual submission of PELVIC MESH PRODUCTS for approval and/or the approval of PELVIC MESH PRODUCTS in another country besides the U.S. including, but not limited to, communications regarding foreign governmental agencies and their drug approval procedures, rules and/or standards, and including any English translations that exist if the DOCUMENTS are written in any language other than English.

23. All DOCUMENTS concerning deferred approval and/or clearance of PELVIC MESH PRODUCTS in any country, including any English translations that exist if the DOCUMENTS are written in any language other than English.

24. All DOCUMENTS concerning standards imposed or recommended by the FDA or any foreign regulatory agency regarding mesh products for use in the human body, including but not limited to any proposed, draft, and/or final regulations regarding particle loss.



25. All DOCUMENTS concerning or relating to any criminal investigations of YOU involving PELVIC MESH PRODUCTS and/or HERNIA MESH PRODUCTS in any country, including any English translations that exist if the DOCUMENTS are written in any language other than English.

26. All DOCUMENTS concerning any regulatory actions or investigations, whether criminal or civil, involving any allegations involving failure to seek or obtain regulatory approval prior to marketing any of YOUR products, including but not limited to PELVIC MESH PRODUCTS and/or HERNIA MESH PRODUCTS. This request includes, but is not limited to, all such documents involving YOUR failure to seek regulatory approval for the ULTRAPRO Hernia Mesh System, and the PROLIFT hernia mesh system.

**Development, Testing and Manufacture of Pelvic Mesh Products**

27. Any agreements among and between Defendants and any other entity or individuals relating to the development, testing, manufacturer, design and/or patents for Pelvic Mesh Products.

28. All DOCUMENTS in YOUR possession, custody, or control pertaining to the safety, adverse events, problems, injuries, malfunctions, complications, and/or defects of Pelvic Mesh Products or Hernia Mesh Products.

29. All DOCUMENTS in YOUR possession, custody, or control pertaining to the efficacy or lack thereof of Pelvic Mesh Products or Hernia Mesh Products.

30. Any DOCUMENTS that identify or list (including in summary format) any completed, proposed, planned, considered, or conceived preclinical studies as well as clinical trials that assess the safety and/or efficacy of PELVIC MESH PRODUCTS.

31. All Preclinical and Clinical Study reports relating to PELVIC MESH PRODUCTS, including all drafts of the same.

32. All Preclinical and Clinical Study protocols relating to PELVIC MESH PRODUCTS, including all drafts of the same.

33. Any DOCUMENTS that identify or list (including in summary format) any completed, proposed, planned, considered, or conceived preclinical studies as well as clinical trials that assess, evaluate or discuss the safety and/or efficacy of PELVIC MESH PRODUCTS.

34. All DOCUMENTS that reflect written procedures for the collection, evaluation or dissemination of adverse event reports concerning PELVIC MESH PRODUCTS.

35. Any electronic database, electronic spreadsheet, or other electronic program in YOUR possession, custody, or control concerning or comprising adverse event reports generated concerning the use of PELVIC MESH PRODUCTS. Responsive materials are to be produced in their native format.

36. All Documents relating to the manufacture of Pelvic Mesh Products, including but not limited to inspection reports and compliance reports.

37. All documents relating to the design of Pelvic Mesh Products, including but not limited to Design Validation Protocols and Patent Applications.

38. All DOCUMENTS in YOUR possession, custody, or control relating to any Standard Operating Procedure (“SOP”) and policy and procedure manuals relating to the manufacture of Pelvic Mesh Products during the relevant time period.

39. All DOCUMENTS constituting and/or summarizing Defendants’ post-marketing adverse event reports for PELVIC MESH PRODUCTS.

40. All MedWatch forms and updates that concern or reference PELVIC MESH PRODUCTS.

41. All DOCUMENTS in YOUR possession, custody, or control comprising or regarding user complaints or concerns pertaining to PELVIC MESH PRODUCTS.

42. All DOCUMENTS in YOUR possession, custody, or control comprising or regarding physician or health care provider complaints or concerns pertaining to PELVIC MESH PRODUCTS.

43. All internal communications regarding adverse events, malfunctions, and/or complications related to PELVIC MESH PRODUCTS.

44. All DOCUMENTS received by Defendants that report an adverse event to Defendants, regardless of the source of such documents, in the original form received by Defendants, excluding any pleadings that initiated litigation against defendants for personal injuries resulting from the use of PELVIC MESH PRODUCTS.

45. All correspondence and/or other communication received from doctors, hospitals, healthcare providers, sales representatives, procurement officers and/or PELVIC MESH PRODUCTS users regarding complaints with PELVIC MESH PRODUCTS and/or adverse events with PELVIC MESH PRODUCTS.

46. All correspondence and/or other communication prepared and/or sent in response to communication received from doctors, hospitals, healthcare providers, and/or PELVIC MESH PRODUCTS users regarding complaints with PELVIC MESH PRODUCTS and/or adverse events with the PELVIC MESH PRODUCTS, including any and all internal communications.

47. All scientific, clinical, and medical literature in YOUR possession, custody or control concerning the safety and/or efficacy of Pelvic Mesh Products or Hernia Mesh Products.

48. All bibliographies relating to Pelvic Mesh Products or Hernia Mesh Products.
49. All DOCUMENTS in YOUR possession, custody, or control comprising or regarding any communication with journals, authors, or publications about any articles, registries, or studies relating to PELVIC MESH PRODUCTS.
50. All DOCUMENTS in YOUR possession, custody, or control comprising or regarding all published and unpublished medical and scientific articles, abstracts, registries, and/or research papers pertaining to PELVIC MESH PRODUCTS.
51. All DOCUMENTS relating, referring to or embodying any epidemiological studies relating to the PELVIC MESH PRODUCTS and the actual or possible health effects of such products on humans and/or animals.
52. All DOCUMENTS in YOUR possession, custody or control containing any data or information relating to published studies (whether sponsored by YOU or not sponsored by YOU) involving PELVIC MESH PRODUCTS.
53. All DOCUMENTS in YOUR possession, custody or control containing any data or information relating to unpublished and discontinued studies (whether sponsored by YOU or not sponsored by YOU) involving PELVIC MESH PRODUCTS.
54. All DOCUMENTS in YOUR possession, custody or control containing any data or information relating to ongoing, past, future, or potential studies and/or registries (whether sponsored by YOU or not sponsored by YOU) involving PELVIC MESH PRODUCTS.
55. All DOCUMENTS in YOUR possession, custody or control related to pre-clinical testing conducted that involves PELVIC MESH PRODUCTS including but not limited to all data concerning animal studies, *in vitro* studies, competitive studies, scientific studies, registries, head-to-head studies, parallel studies, randomized controlled trials, and/or double blind studies.

56. All DOCUMENTS, including, but not limited to, notebooks and electronic notebooks in YOUR possession, custody or control, provided to clinical investigators or scientists that pertain to past, present, and future pre-clinical and clinical studies of PELVIC MESH PRODUCTS.

57. All DOCUMENTS in YOUR possession, custody, or control comprising or regarding YOUR internal communications pertaining the safety and/or efficacy of PELVIC MESH PRODUCTS.

58. All DOCUMENTS in YOUR possession, custody, or control relating to any SOP and policy and procedure manuals relating to YOUR post-marketing surveillance for PELVIC MESH PRODUCTS during the relevant time period.

59. All DOCUMENTS in YOUR possession, custody, or control relating to any SOP and policy and procedure manuals relating to YOUR clinical and pre-clinical trials for PELVIC MESH PRODUCTS during the relevant time period.

60. All DOCUMENTS in YOUR possession, custody, or control setting forth any SOP, policy, and procedure concerning adverse event reporting, complaints, or concerns from physicians, health care facilities, sales persons and representatives, and consumers, and the reporting of such concerns within YOUR company, and to the FDA, and/or to any other regulatory body, during the relevant time period.

61. All internal communications concerning what information should be provided to consumer, physicians or other healthcare professionals concerning the safety risks and/or efficacy of PELVIC MESH PRODUCTS including, but not limited to, draft and approved informed consent forms.

62. All DOCUMENTS in YOUR possession, custody, or control constituting minutes from meetings, summaries of the minutes of such meetings, agendas for such meetings, presentations made at any such meetings (in their native format) and/or summaries of such meetings with any and all physicians and investigators involved with clinical and pre-clinical trials for PELVIC MESH PRODUCTS.

63. All DOCUMENTS in YOUR possession, custody, or control from physicians and/or investigators concerning all PELVIC MESH PRODUCTS clinical or pre-clinical trials provided to YOU, whether provided to the FDA or not.

64. All DOCUMENTS in YOUR possession, custody, or control comprising or regarding the retention and/or use of any third-parties who have analyzed or re-analyzed the safety and/or efficacy of PELVIC MESH PRODUCTS.

65. All DOCUMENTS in YOUR possession, custody, or control comprising or regarding compensation, honoraria, grants, scholarships, or gifts, offered or paid, to individuals or institutions for work associated with PELVIC MESH PRODUCTS, including, but not limited to, the promotion, marketing, research, pre-clinical and clinical trial investigation, and the authorship of articles related to or concerning PELVIC MESH PRODUCTS.

66. All DOCUMENTS and/or databases in YOUR possession, custody, or control comprising or regarding any committee, task force, or group YOU created or participated in to address or handle questions or concerns related to the safety and/or efficacy of PELVIC MESH PRODUCTS.

67. All DOCUMENTS relating to any meetings of the Global Safety Board or predecessor organization relating to or concerning PELVIC MESH PRODUCTS or HERNIA

MESH PRODUCTS, including but not limited to final and draft minutes from meetings, summaries of the minutes of such meetings, and agendas for such meetings.

68. All DOCUMENTS concerning the manufacturing process utilized in making PELVIC MESH PRODUCTS.

69. All DOCUMENTS concerning any changes to the manufacturing process utilized in making PELVIC MESH PRODUCTS that were considered and/or proposed but were not implemented.

70. All DOCUMENTS concerning the design of PELVIC MESH PRODUCTS.

71. All DOCUMENTS concerning any changes to the design of PELVIC MESH PRODUCTS that were considered and/or proposed but were not implemented.

72. All DOCUMENTS concerning a comparison of the safety between PELVIC MESH PRODUCTS and other treatments and/or products used for pelvic floor repair or stress urinary incontinence.

73. All DOCUMENTS concerning a comparison of the efficacy between PELVIC MESH PRODUCTS and other treatments and/or products used for pelvic floor repair or stress urinary incontinence.

74. All DOCUMENTS comparing the safety and/or efficacy of YOUR PELVIC MESH PRODUCTS to each other, or to those of another manufacturer.

75. All DOCUMENTS concerning or relating to any studies, including but not limited to all phases, drafts, protocols, notes, comments, interim reports, final reports, and versions thereof, whether published or not, that suggest, raise question about, indicate or demonstrate a result that evaluates the safety of PELVIC MESH PRODUCTS.

76. All consulting agreements, engagement agreements, employment agreements, or any other agreement, however titled, relating in any way the testing, research, development, and/or evaluation that in any way relates or concerns PELVIC MESH PRODUCTS.

77. All Quality Control and/or Quality Assurance policies and/or procedures in place at any time YOU developed, marketed or sold PELVIC MESH PRODUCTS.

**Marketing, Promotion, and Training Relating to Pelvic Mesh Products**

78. All draft and final package inserts, product labels, and instructions for use provided for any Pelvic Mesh Products and Hernia Mesh Products during the relevant time period.

79. All final Core Data Sheets relating to Pelvic Mesh Products and Hernia Mesh Products approved during the relevant time period.

80. All draft and final form Dear Doctor/Healthcare Provider Letters prepared by Defendants regarding Pelvic Mesh Products or Hernia Mesh Products.

81. All draft and final patient and/or consumer information sheets and brochures relating to Pelvic Mesh Products.

82. All draft and final detail aids, physician information sheets, physician brochures, and/or physician marketing and promotional materials relating to Pelvic Mesh Products.

83. All documents, including promotional and marketing materials, intended to be left by sales representatives in the offices of healthcare professionals relating to Pelvic Mesh Products.

84. All draft and final documents and/or materials relating to physician training for Pelvic Mesh Products.



85. All documents that index or catalog Defendants' approved or draft advertising, sales and marketing materials, and print and broadcast advertisements, sales aids, visuals, sales scripts, sales guides, and reminder pieces relating to Pelvic Mesh Products.

86. All documents relating to, submitted to, created by, or concerning any committee that reviews and approves any labeling, advertising, sales and marketing materials, or external communications relating to Pelvic Mesh Products.

87. All documents concerning or relating to marketing plans for PELVIC MESH PRODUCTS, including but not limited to the Global Launch Plans for each PELVIC MESH PRODUCT.

88. Video files (in video format) of all television advertisements, including drafts, for PELVIC MESH PRODUCTS, produced on DVD.

89. Audio files (in audio format) of all radio advertisements, including drafts, for PELVIC MESH PRODUCTS on CD or DVD.

90. Documents sufficient to identify all advertising agencies or public relations firms utilized by Defendants in connection with PELVIC MESH PRODUCTS in the United States.

91. All DOCUMENTS showing or proving that an PELVIC MESH PRODUCTS advertisement was run on either television or radio, or placed in print media, including but not limited to affidavits received from the media outlets, media buyers, or YOUR advertising agencies or public relations firms.

92. All Documents relating to any Direct-to-Consumer marketing and/or advertising campaigns relating to PELVIC MESH PRODUCTS.

93. Copies of all print advertisements, including drafts, for PELVIC MESH PRODUCTS.

94. All DOCUMENTS relating to event advertising for PELVIC MESH PRODUCTS.

95. All DOCUMENTS pertaining to any focus groups or surveys relating to Pelvic Mesh Products.

96. Copies in electronic/navigatable format of any Web page or Website maintained by or on behalf of Defendants that contains any content relating to PELVIC MESH PRODUCTS.

97. Screenshots of all Internet based advertisements (including but not limited to Web sites, blogs, bulletin boards, and pod-casts) or e-commerce information relating to PELVIC MESH PRODUCTS sponsored by or on behalf of Defendants, including every screen within any Website.

98. All DOCUMENTS that identify former and/or present sales representatives or detail persons responsible for, or involved with, the marketing or selling of PELVIC MESH PRODUCTS, including the territory each was responsible for.

99. All DOCUMENTS used in the training of YOUR sales force and sales representatives who promoted or sold PELVIC MESH PRODUCTS at any point in time.

100. All audio files and video files (in native format) used in the training of your sales force and sales representatives relating to PELVIC MESH PRODUCTS, produced on separate DVD.

101. All transcripts of any audio files and video files used in the training of your sales force and sales representatives relating to PELVIC MESH PRODUCTS.

102. All audio communications (both in audio file format and a transcript of the same) between YOU and YOUR sales force relating to PELVIC MESH PRODUCTS.

103. All email or other written communications between YOU and YOUR sales force relating to PELVIC MESH PRODUCTS.

104. Any database maintained by or on behalf of Defendants that contains sales call notes and field notes relating to PELVIC MESH PRODUCTS by your sales force.

105. Any database maintained by or on behalf of Defendants that contains data concerning the number of prescriptions or orders written by any physician or health care provider relating to PELVIC MESH PRODUCTS.

106. All DOCUMENTS that contain information created by any sales representative or detail person concerning PELVIC MESH PRODUCTS that were created related to a meeting or conversation with any doctor, pharmacist or healthcare professional.

107. All DOCUMENTS that reflect warnings, objections or criticisms by any United States governmental or regulatory entity of YOUR marketing and/or promotional materials or practices for PELVIC MESH PRODUCTS.

108. All DOCUMENTS that reflect written procedures or guidelines for sales persons or detail people for recording information about doctor and healthcare provider detail visits.

109. All DOCUMENTS concerning or regarding the training of YOUR sales persons or detail people who worked on PELVIC MESH PRODUCTS.

110. All DOCUMENTS concerning or regarding the compensation scheme for YOUR sales person or detail people who worked on PELVIC MESH PRODUCTS.

111. DOCUMENTS sufficient to identify Defendants' thought leaders and/or key opinion leaders including, but not limited to, doctors and healthcare providers who were offered and/or receive payment or honoraria from Defendants for preparation of scientific papers,

posters, medical articles, speeches, lectures, and/or presentations regarding PELVIC MESH PRODUCTS.

112. All DOCUMENTS in YOUR possession, custody, or control comprising or regarding YOUR internal communications pertaining to PELVIC MESH PRODUCTS's past, present, and future anticipated market share and/or sales in the United States.

113. All DOCUMENTS in YOUR possession, custody, or control comprising or regarding YOUR internal communications pertaining to PELVIC MESH PRODUCTS's past, present, and future anticipated market share and/or sales worldwide.

114. All DOCUMENTS in YOUR possession, custody, or control relating to any SOP and policy and procedure manuals relating to the content and format of labeling for PELVIC MESH PRODUCTS during the relevant time period.

115. All DOCUMENTS in YOUR possession, custody, or control relating to any SOP and policy and procedure manuals relating to Dear Doctor or Health Advisory Letters concerning or regarding PELVIC MESH PRODUCTS during the relevant time period.

116. All DOCUMENTS in YOUR possession, custody, or control relating to any SOP and policy and procedure manuals relating to the content and format of package inserts, patient information sheets, and other information pertaining to or concerning PELVIC MESH PRODUCTS during the relevant time period.

117. All DOCUMENTS in YOUR possession, custody, or control intended to be provided to prescribing physicians regarding PELVIC MESH PRODUCTS and its intended use, contraindications, and potential complications.

118. All DOCUMENTS concerning the relationship between Defendants and any outside person or entity involved in the market analysis, marketing, advertising, or promotion of

PELVIC MESH PRODUCTS, including but not limited to the contracts between Defendants and such person or entity, communications, and any invoices for services rendered.

119. All DOCUMENTS concerning YOUR annual sales revenue derived from PELVIC MESH PRODUCTS in the United States and broken down by State for every year since PELVIC MESH PRODUCTS was first marketed and sold in the United States.

120. All DOCUMENTS concerning YOUR annual profits derived from PELVIC MESH PRODUCTS in the United States and broken down by State for every year since PELVIC MESH PRODUCTS was first marketed and sold in the United States.

121. Any and all media and/or news reports relating to PELVIC MESH PRODUCTS in YOUR possession, custody or control. If responsive materials are television news reports (*e.g.* 20/20, Dateline, local evening news, etc.) produce the native video file of such reports.

122. All DOCUMENTS or information relating to the marketing of PELVIC MESH PRODUCTS through any internet-based website, email campaign, or any other use of the internet or electronic communication.

123. All DOCUMENTS, notes, videos, or other information relating to PELVIC MESH PRODUCTS on Defendant sponsored, supported, edited, and/or linked websites, FaceBook pages, MySpace pages, Twitter pages, Wikipedia or pages on any other websites.

124. Copies of all information relating to the marketing of PELVIC MESH PRODUCTS by Defendants through chat rooms and women's health-related websites or forums, and other social networking media.

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